providing the sample of blood within the blood collection tube;

manipulating the blood collection tube to separate the light serum portion of the blood sample from the heavy cellular portion of the blood sample.

REMARKS

This application has been reviewed in light of the Office Action dated October 18, 2002. Claims 1, 3-11 and 14-30 are pending in the application. Claims 1, 3-11 and 14-29 are amended in a manner that Applicant believes overcomes the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicant is believed to be entitled. No new matter or issues are believed to be introduced by the amendments.

Initially, Applicant would like to thank Examiner Kim for a telephone conference with the undersigned on January 21, 2003 to clarify issues to be resolved during further prosecution of the present application.

In the Office Action, claims 1, 3-5, 14, 16, 18-25, 27 and 28 were rejected under 35 U.S.C. §102(e) by U.S. Patent No. 5,853,600 to McNeal et al. (McNeal '600). However, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, amended independent claim 4, claims 5-18 ultimately depending therefrom, amended independent claim 19, claim 20 depending therefrom, amended independent claim 21 and claims 22-29 ultimately depending therefrom, clearly and patentably distinguish over McNeal '600.

Referring to FIGS. 1-11, McNeal '600 discloses a blood separation system having a tube 10 with longitudinally extending ribs 20 (col. 2, lines 60-63), employed during axial centrifugation (col. 1, lines 44-46), as compared to conventional centrifugation (col. 2, lines 10-12). McNeal '600 requires:

> *Specifically, the gel is introduced into the tube and axial centrifugation is performed, i.e. the tube is spun about its longitudinal axis. The axial centrifugation causes the gel to be*

> *distributed about the tube, along the inside wall of the tube and to settle mostly within channels between the ribs of the tube. This step allows the gel to be distributed evenly* ***throughout*** *the tube and contributes to quick, even separations.* (col. 1, lines 44-50) (Emphasis added).

Concentric shells 24 (gel), 28 (blood cells), 30 (plasma) extend longitudinally along the entire length of tube 10 to separate portions of a blood sample, as shown in FIGS. 5 and 9. (col. 1, lines 52-54, col. 5, lines 1-8 and 32-35).

In contrast, amended claims 1, 4 and 19 of the present application recite, *inter alia*, "...[a] blood collection apparatus comprising...a blood collection tube defining...a closed end; and a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being selectively deposited on the inner surface, and displaced a distance relative to the end..." The distance being based on predetermined limits.

In further contrast, amended method claim 21 of the present application recites, *inter alia*, "...[a] method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the method comprising the steps of...providing a blood collection tube defining...a closed end; providing a dispensing apparatus configured to dispense a thixotropic gel, being configured to form a transverse barrier between the light serum portion and the heavy cellular portion of a blood sample during centrifugation, the gel being deposited along a portion of the central inner surface and displaced a distance relative to the closed end, said distance based on the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of the blood sample being collected; depositing the gel for centrifugation via the dispensing apparatus along the portion of the central inner surface..."

McNeal '600 in no way discloses or suggests a structure as recited in amended claims 1, 4 and 19, or a method as disclosed in amended method claim 21. McNeal '600 does not disclose, *inter alia*, a blood collection apparatus having a blood collection tube defining a closed end and a thixotropic gel being to form a transverse barrier between a lighter phase and a heavier phase of

a blood sample during centrifugation, the gel being selectively deposited on the inner surface, and displaced a distance relative to the end. The distance being based on predetermined limits. Rather, McNeal '600 shows an axial centrifugation blood separation system that forms concentric shells along the entire longitudinal length of a tube.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, amended independent claim 4, claims 5-18 ultimately depending therefrom, amended independent claim 19, claim 20 depending therefrom, amended independent claim 21 and claims 22-29 ultimately depending therefrom are patentable and not obvious over McNeal '600 for at least the reasons outlined hereinabove. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, the subject matter of claims 6-11, 15, 17, 26, 29 and 30 were found allowable. Applicant respectfully submits that in view of the above amendments and remarks all claims presently pending in the application are allowable over the art of record.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1, 3-11 and 14-30 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant's undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,

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APPENDIX I

1. (Amended) A blood collection apparatus comprising:

a blood collection tube defining an inner surface and [an] a closed end; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being selectively [dispensed for centrifugation along] deposited on the inner surface, and displaced a distance relative to the end, said distance based on at least one dimension of the blood collection tube and a volume of the blood sample being collected.

4. (Amended) A blood collection apparatus comprising:

a blood collection tube defining a central inner surface and [an] a closed end; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being [dispensed for centrifugation along] deposited on a portion of the central inner surface and displaced a distance relative to the closed end, said distance based on the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and the volume of a blood sample being collected.

19. (Amended) A blood collection apparatus comprising:

means for collecting a sample of blood defining a central inner surface and a closed end; and

a thixotropic gel being configured to form a transverse barrier between a lighter phase and a heavier phase of a blood sample during centrifugation, the gel being [dispensed for

centrifugation along] deposited on a predetermined portion of the central inner surface and displaced a distance relative to the closed end, said distance based on the predetermined portion [being] that is predetermined based on at least one dimension of the means for collecting a blood sample and a volume of the blood sample being collected.

21. (Amended) A method for separating a sample of blood into portions including a light serum portion and a heavy cellular portion, the method comprising the steps of:

providing a blood collection tube defining a central inner surface and [an] a closed end;

providing a dispensing apparatus configured to dispense a thixotropic gel, being configured to form a transverse barrier between the light serum portion and the heavy cellular portion of a blood sample during centrifugation, the gel being deposited along a portion of the central inner surface and displaced a distance relative to the closed end, said distance based on the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end, the limits being predetermined based on at least one dimension of the blood collection tube and a volume of the blood sample being collected;

[dispensing] depositing the gel for centrifugation via the dispensing apparatus along the portion of the central inner surface;

providing the sample of blood within the blood collection tube;

manipulating the blood collection tube to separate the light serum portion of the blood sample from the heavy cellular portion of the blood sample.